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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/960,454	09/21/2001	Michael D. Uhler	UM-06617	5780

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EXAMINER

NGUYEN, QUANG

ART UNIT PAPER NUMBER

1636

DATE MAILED: 10/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/960,454	Applicant(s) UHLER, MICHAEL D.	
	Examiner Quang Nguyen, Ph.D.	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 and 37-49 is/are pending in the application.
- 4a) Of the above claim(s) 1-33 and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/16/04;3/4/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment filed on 7/19/04 has been entered.

Claims 1-33, 37 and new claims 38-49 are pending in the present application.

This application contains claims 1-33 and 37 drawn to an invention nonelected with traverse in the Response to the restriction requirement dated 1/22/03. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Accordingly, new claims 38-49 are examined on the merits herein.

Response to Amendment

The rejections in the Office Action mailed on 7/2/04 are withdrawn in light of Applicant's amendment in the form of new claims 38-49.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 4/16/04 and 3/4/04 was filed after the mailing date of the Office Action on 9/10/03. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New claims 38-49 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of claim 38 using a eukaryotic cell, does not reasonably provide enablement for a method of claim 38 using any cell, including a prokaryotic cell as encompassed by the instant claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

This is a new ground of rejection necessitated by Applicants' amendment.

The factors to be considered in the determination of an enabling disclosure have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art and the breadth of the claims. *Ex parte Forman*, (230 USPQ 546 (Bd Pat. Appl & Unt, 1986); *In re Wands*, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)).

The instant specification is not enabled for the present broadly claimed invention for the following reasons.

(1) The breadth of the claims.

The claims are drawn to a method in which both eukaryotic and prokaryotic cells are used to detect the presence or absence of binding between a receptor protein expressed by a first nucleic acid and a test protein expressed by a second nucleic acid in a transfection complex immobilized on a surface.

(2) The state and the unpredictability of the prior art.

At about the effective filing date of the present application, the art on introducing DNA of interest that is immobilized on a multi-well surface into any cells (or reverse transfection method), let alone prokaryotic cells, was relatively nascent (Sabatini, U.S. Patent No. 6,544,790 IDS; Ziauddin et al., Nature 411:107-110, 2001). Additionally, it is uncommon in the prior art that prokaryotic or bacterial cells are transformed or transfected by simply being in contact with any nucleic acid molecule in a transfection complex, particularly since it is well known that prokaryotic cells possess a tough protective cell coat or cell wall, let alone the nucleic acid complex is immobilized on a surface. Furthermore, it should be noted that the physiological art is recognized as unpredictable (MPEP 2164.03).

(3) *The amount of direction or guidance provided.*

Apart from the exemplification showing that eukaryotic cells are capable of being transfected by the methods of the presently claimed invention, the instant specification fails to provide sufficient guidance for a skilled artisan on how to transfect any prokaryotic cells in the same manner. It is not clear whether prokaryotic cells behave in the same manner as eukaryotic cells, so that they can also be transfected upon simply contacting the prokaryotic cells with a nucleic acid in a transfection complex immobilized on a surface. Since the prior art at the effective filing date of the present application does not provide such guidance, it is incumbent upon the present application to do so. Given the lack of sufficient guidance provided by the present disclosure and in light of the state of the prior art discussed above, it would have required undue experimentation for a skilled artisan to make and use the methods as claimed.

(4) Working examples.

There is no example in the present disclosure showing that bacterial cells or prokaryotic cells are also capable of being transfected under any culture conditions by any immobilized transfection complex, let alone for detecting the presence or absence of binding between a receptor protein expressed by a first nucleic acid and a test protein expressed by a second nucleic acid in the immobilized transfection complex.

Accordingly, due to the lack of sufficient guidance provided by the specification regarding to the issue set forth above, the unpredictability of the physiological art, and the breadth of the claims, it would have required undue experimentation for one skilled in the art to make and use the instant broadly claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 40 and its dependent claim 41, there is no relationship or connection between a reporter gene assay with the presence or absence of binding between an encoded receptor protein and an encoded test protein, especially when the test protein is a transcriptional factor that is capable of binding to a cAMP response element operably linked to a selectable marker. Clarification is requested because the metes and bounds of the claims are not clearly determined.

Claim 41 recites the limitation "said reporter gene" in line 1. There is insufficient antecedent basis for this limitation in the claim. This is because in claim 40 from which claim 41 is dependent on, there is no recitation of any reporter gene, only a reporter gene assay. Therefore, the metes and bounds of the claim are not clearly determined.

Examiner's Comments

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Sabatini (US 6,544,790; IDS) disclose a reverse transfection method of introducing DNA of interest into cells and arrays, including microarrays, of reverse transfected cells. However, Sabatini does not teach or fairly suggest any co-transfection of nucleic acids at each discrete and defined location of the array, let alone the first nucleic acid encoding a receptor protein and a second nucleic acid encoding a test protein that is tested for its ability to bind to the receptor protein as claimed by the present invention.

Sabatini (US 2003/0228694 A1) is not considered as a prior art because the provisional application No. 60/193,580 with the earlier filing date of March 30, 2000 does not have the support for the co-transfection nucleic acids at each discrete and defined location of a transfected cell array.

Accordingly, the instant claims are free of the prior art of record.

Conclusions

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, David Guzo, Ph.D., may be reached at (571) 272-0767, or SPE, Irem Yucel, Ph.D., at (571) 272-0781.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1636; Central Fax No. (703) 872-9306.


Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now

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Quang Nguyen, Ph.D.


DAVID C. LUGO
PRIMARY EXAMINER